IN THE CLAIMS:

The pending claims are listed in the attached:

Appendix A1: Pending claims (clean copy).

☐ Changes in the pending claims relative to the last version of record are reflected in:

Appendix A2: Changes to claims (version with markings to show changes made, i.e., redline).

REMARKS

Reconsideration of the rejections is respectfully requested.

The status of the claims is as follows:

Amended:	None
Cancelled:	None
New:	None
Pending:	1,2, 13-16
Allowed:	None

Priority

Applicant acknowledges the oversight in the priority claim identified by the Examiner. The error in the priority recitation is corrected herein.

Claim Rejections - 35 U.S.C. §112, First Paragraph

Claims 1,2 and 13-16 stood rejected under 35 U.S.C. §112, first paragraph, based on an assertion that the *in vivo* applications within the claims were not sufficiently enabled. Applicant respectfully, but emphatically, traverses.

One assertion by the Office is that *in vivo* transfections can give rise to immune responses. One of ordinary skill, he or she who is to be enabled, is charged with knowledge of the art. And the problem asserted by the Office is well known and extensively addressed in the art – and has been so addressed from well before any priority date of this application. There are

more than sufficient vectors in the art which are not disabled in their effect by an immune response.

But more simply: vector-based vaccines were known and desirable. This is an application of the invention. Thus, in the context of nucleic acid-based vaccines, an immune response is desirable. Thus, the invention is enabled to one skilled in the art for use in such vaccines. At the very least, a use described in the specification (1:29-31) is credible - hence this rejection cannot be maintained. See, MPEP 2107.02.

In view of the above remarks, Applicant respectfully submits that the rejection should be withdrawn.

Claim Rejections - 35 U.S.C. §103(a)

Claims 1,2 and 13-16 stand rejected under 35 U.S.C. §103(a), based on Donovan (US 5,833,651). Applicant respectfully traverses.

In a preliminary aspect of this traversal, Applicant respectfully notes that to the extent the Office Action at page 6 suggests that Donovan has any teaching at column 13 regarding using fibrin with respect to anything other than a stent, that suggestion is in error. Applicant respectfully submits that a careful reading of the cited text finds no such teaching. Moreover, if the Office draws implications from the use in Donovan of "fibrin monomer," such is also in error. The present application uses the term with a specific meaning provided at page 19: the fibrin is stabilized in essentially non-polymerized form. Nothing in Donovan suggests or indicates this meaning. Thus, the term "fibrin monomer" in Donovan has no implications as to the same words (with a clearly different meaning) recited in the specification.

In the rejection, the Office in hindsight concludes what is not suggested in Donovan: that it would be desirable to entrap nucleic acid in a pliable fibrin gel adhered to a cell. But, the suggestion to modify must come from the prior art, not the comfort taken from the roadmap to the invention provided by the Applicant's specification.

To find motivation to combine or modify in the prior art, that prior art must provide evidence that the combination or modification would have been viewed as desirable in the

context of the prior art teachings. See, MPEP 2143.01. This desirability must be evidenced by more than a conclusion that the alleged combination is feasible. Id.

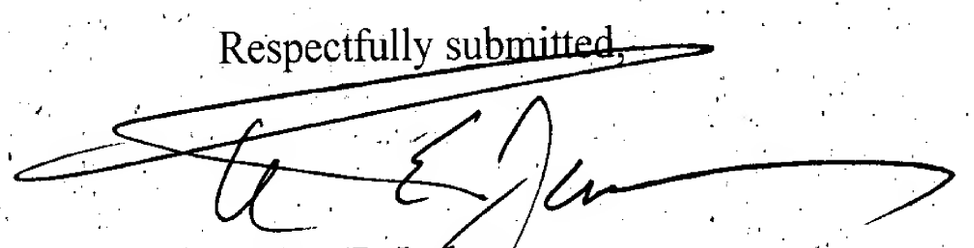
Relatively recently, in Winner International Royalty Corp. v. Wang, the Federal Circuit applied this desirability standard to uphold the validity of claimed subject matter where different references separately disclosed each element of a claimed invention. Winner, 202 F.3d 1340, 53 USPQ2d 1580 (Fed. Cir. 2000) (attached as Exhibit B-3), cert. denied, 530 US 1238. In Winner, the claims at issue were directed to a "Club"-like automobile anti-theft device locked in place across a steering wheel by a self-locking, ratcheting mechanism. References presented at trial disclosed (1) a similar anti-theft device that used a dead-bolt mechanism instead of the ratcheting mechanism, (2) a "Y-shaped" anti-theft device mounted on the steering wheel that used a ratcheting mechanism and (3) other pedal-mounted anti-theft devices that can accommodate either a ratcheting or a dead bolt mechanism. Accordingly, the Federal Circuit found that the first reference disclosed "virtually all aspects claimed" except the ratcheting mechanism. Winner at 1349, 53 USPQ2d at 1587. The second reference disclosed the ratcheting mechanism and the third group of references "may have informed one of ordinary skill in the art that both mechanisms would work." Winner at n. 7. However, the references did not suggest that one mechanism *should* be replaced with another. Winner at n. 7. The Federal Circuit concluded that one of reasonable skill in the art may well have not elected to trade the superior security of a dead-bolt mechanism for the superior convenience of a ratcheting mechanism: "[t]rade-offs often concern what is feasible, not what is, on balance, desirable. Motivation to combine requires the latter." Winner at 1349. Accordingly, the Federal Circuit held that claimed device with ratcheting mechanism was not obvious under 35 U.S.C. §103.

The Office Action provides no evidence of desirability. This shortfall applies to all of the claims. As to claims 15 and 16, however, the lack of any sort of motivation to take the extra steps of using fibrin monomer (which has nothing to do with Donovan's "monomer") or in particular acid-solubilized fibrin, is even more apparent. The rejection, accordingly, should be withdrawn.

Conclusion

In light of the above discussion and amendments, it is respectfully submitted that the claims are in condition for allowance. The issuance of a Notice of Allowance is earnestly solicited.[2]

Respectfully submitted,



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[2] **FEE DEFICIENCY**

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APPENDIX A1: PENDING CLAIMS (CLEAN COPY)

1. (Unchanged, Previously Once Amended) A method of transforming a cell comprising the steps of:

applying a transformation effective amount of a nucleic acid to the cell;

adhering a pliable, adhesive fibrin gel to the cell so as to entrap a transformation effective amount of the nucleic acid in the fibrin gel adhered to the cell; and

transforming the cell with the nucleic acid.

2. (Unchanged, Previously Once Amended) The method of claim 1, wherein the nucleic acid is applied in admixture with a fibrin or fibrinogen composition that forms the pliable, adhesive fibrin gel.

13. (Unchanged) The method of claim 1, wherein the nucleic acid is a plasmid.

14. (Unchanged) The method of claim 1, wherein the nucleic acid is incorporated in a virus.

15. (Unchanged) The method of claim 1, wherein the pliable, adhesive fibrin gel is formed by mixing a fibrin monomer composition with a polymerizing agent preparation effective to convert the fibrin monomer preparation into a fibrin gel, and adhered by contacting the cell with the mixture while the mixture is pliable and adhesive.

16. (Unchanged) The method of claim 15, wherein the fibrin monomer composition comprises acid-solubilized fibrin, and the polymerizing agent comprises an amount of base effective to sufficiently neutralize the mixture to allow the fibrin to polymerize.

APPENDIX B1: REPLACEMENT PARAGRAPHS (CLEAN COPY)

At page 1, first paragraph: Please change to the following:

C 1

This application claims the priority of US Provisional Application 60/089,543, filed June 17, 1998, and is a continuation of US Application 09/303,377, filed April 30, 1999.

APPENDIX B2: REPLACEMENT PARAGRAPHS (VERSION WITH MARKINGS TO SHOW CHANGES MADE, I.E., REDLINE)

At page 1, first paragraph: Please change to the following:

This application claims the priority of US Provisional Application 60/089,543, filed June 17, 1998, and is a continuation of US Application 09/303,377, filed April 30, 1999.